

**Notice of Allowability**

Application No.

10/758,572

Applicant(s)

COHEN-VERED ET AL.

Examiner

Anand U. Desai, Ph.D.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to June 25, 2007.
2. ☒ The allowed claim(s) is/are 12,13,15-19,21,31,32,41-43,52,53 and 57-66.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20070722</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____.   |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2007 has been entered.
2. Claims 1-11, and 14 have been cancelled. New Claims 62-65 have been added.
3. Claims 12, 13, 15-19, 21, 31, 32, 41-43, 52, 53, and 57-65 are currently pending and are under examination.

### **Withdrawal of Rejections**

4. The rejection of claims 12, 13, 15-19, 21, 31, 32, 41, 42, 52, 53, and 57-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 16, 24, 25, 27, 36, 37, 47, and 52 of copending Application No. 10/758,397 (U.S. Patent Application Publication 2005/0008634 A1) is withdrawn.
5. The rejection of claims 19, 21, and 31 under 35 U.S.C. 103(a) as being unpatentable over Mozes U.S. 2004/0127408 A1 (Priority date = February 26, 2001) in view of Hora et al. U.S. Patent 5,997,856 is withdrawn based on the amendments to the claims.
6. The rejection of claims 12, 13, and 15-18 under 35 U.S.C. 103(a) as being unpatentable over Mozes U.S. 2004/0127408 A1 (Priority date = February 26, 2001) in view of Hora et al.

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U.S. Patent 5,997,856, and further in view of Stella et al. U.S. Patent 5,134,127 is withdrawn based on the amendment to the claims.

### **EXAMINER'S AMENDMENT**

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Gary Gershik on July 19, 2007.

Examiner's amendment to the claims:

In claim 21, please remove ---of claim 12---

In claim 21, please replace in step a) the phrase, "substituted  $\beta$ -cyclodextrin or a salt thereof" with ---hepta-(sulfobutyl ether)-  $\beta$ -cyclodextrin or a salt of hepta-(sulfobutyl ether)-  $\beta$ -cyclodextrin---.

Claim 66 (New) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 0.5 mg/ml.

### ***Allowable Subject Matter***

8. Claims 12, 13, 15-19, 21, 31, 32, 41-43, 52, 53, and 57-66 are allowed.

9. The following is an examiner's statement of reasons for allowance: The prior art does not anticipate or render obvious the pending claims because the prior art does not teach all the

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elements of the claims, and the prior art does not teach selection of the hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin with the peptide currently claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 22, 2007

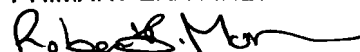
AD

/Anand Desai/

Patent Examiner

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ROBERT MONDESI  
PRIMARY EXAMINER



7-23-07